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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,061	09/05/2003	Jerome Legerton	QLT.002A	9098

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EXAMINER

STULTZ, JESSICA T

ART UNIT	PAPER NUMBER
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2873

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/657,061	Applicant(s) LEGERTON ET AL.	
	Examiner Jessica T. Stultz	Art Unit 2873	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 and 62-71 is/are pending in the application.
- 4a) Of the above claim(s) 12-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 44-51 and 62-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0505</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

Claims 63-71 are objected to under 37 CFR 1.75 as being substantially duplicate claims of claims 1 and 3-10. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Specifically, the only difference between claim 63 (as it depends from claim 62) and independent claim 1 is that the term DK is replaced by the definition of DK, gas permeability (Specification, page 7, lines 3-5). Therefore these terms have the exact same meaning, with a slight difference in wording and claim 63 is a duplicate of claim 1.

Claim Objections

Claim 64 is objected to because of the following informalities: in line 1, “lens of claim 62” should be “lens of claim 63” since there are no angled surfaces in claim 62, however, there is an angled surface in claim 63. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 62 and 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by

Domschke et al.

Art Unit: 2873

Regarding claim 62, Domschke et al discloses a hybrid contact lens (Column 20, lines 4-22, wherein the lenses are hybrid contact lenses), comprising: a substantially rigid portion having a gas permeability value of at least 30×10^{-11} (cm²/sec) (mL O₂) / (mL x mm Hg) (Column 29, lines 23-54, wherein the rigid portion of the plasma treated lens has a gas permeability of 90); and a substantially flexible hydrophilic portion coupled to the substantially rigid portion at a junction (Column 17, line 37-Column 18, line 21 and Column 20, lines 4-22, wherein the lens is coated with a hydrophilic polymeric flexible material and the coating is therefore coupled to the rigid portion at a junction).

Regarding claims 67-69, Domschke et al further discloses that the rigid portion has a gas permeability in the claimed range (Column 29, lines 23-54, wherein the rigid portion of the plasma treated lens has a gas permeability of 90), wherein the rigid portion is made of dimethylacrylamide (Column 26, lines 8-32, wherein the lens (Column 29, lines 23-54 is made according to example B1, including dimethylacrylamide), and wherein the hydrophilic portion includes poly HEMA (Column 14, line 34-Column 15, line 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 44-51, 63-66, and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domschke et al, as shown above regarding claims 62 and 67-69, in view of Sohnges.

Specifically regarding claims 1, 11, and 63, Domschke et al discloses a hybrid contact lens (Column 20, lines 4-22, wherein the lenses are hybrid contact lenses), comprising: a substantially rigid portion having a gas permeability value of at least 30×10^{-11} (cm²/sec) (mL O₂)/(mL x mm Hg) (Column 29, lines 23-54, wherein the rigid portion of the plasma treated lens has a gas permeability of 90); and a substantially flexible hydrophilic portion coupled to the substantially rigid portion at a junction (Column 17, line 37-Column 18, line 21 and Column 20, lines 4-22, wherein the lens is coated with a hydrophilic polymeric flexible material and the coating is therefore coupled to the rigid portion at a junction), but does not specifically disclose that the junction comprises an angled surface or a surface with at least two intersecting planes. Sohnges teaches of a hybrid contact lens (Column 4, line 113-Column 5, line 20, wherein the contact lens shown has two parts, specifically a hard portion “4” and a flexible portion “3”, Figures 1-2) comprising: a substantially rigid portion (Column 4, line 113-Column 5, line 20, wherein the contact lens shown has a hard, rigid portion “4”, Figures 1-2); and a substantially flexible portion coupled to the substantially rigid portion at a junction (Column 4, line 113-Column 5, line 20, wherein the hard, rigid portion “4” is coupled to the flexible portion “3”, Figures 1-2); wherein the junction comprises an angled surface and at least two intersecting planes (Shown in Figures 1-2) for the purpose of providing a lens capable of supplying a sufficient amount of oxygen to the user and to provide a lens that is compatible with users and impermeable to bacteria (Column 3, line 62-Column 4, line 78). Therefore it would have been obvious for the lens of Domschke et al to further include the junction between the rigid and flexible portions to include an angled surface and at least two intersecting planes since Sohnges teaches of a hybrid contact lens comprising: a substantially rigid portion; and a substantially

Art Unit: 2873

flexible portion coupled to the substantially rigid portion at a junction; wherein the junction comprises an angled surface and at least two intersecting planes for the purpose of providing a lens capable of supplying a sufficient amount of oxygen to the user and to provide a lens that is compatible with users and impermeable to bacteria.

Regarding claims 2-5, 44-46, and 64-66 Domschke et al and Sohnges disclose and teach of a contact lens as shown above and Sohnges further disclose that the angled surface comprises a substantially V-shaped surface (Figure 2), wherein the angled surfaces are angled between about 95 degrees to about 170 degrees, (Figure 2), wherein the rigid portion has a diameter that ranges between 4.0 millimeters to about 12.0 millimeters (Column 3, lines 5-6, wherein the lens core has a diameter of 6-10 mm, which falls within the given range) and wherein the substantially flexible portion has an outer diameter that ranges between about 10.0 millimeters to about 18.0 millimeters (Column 3, lines 5-6 and Column 3, line 120-Column 4, line 20, wherein the lens core is 10 mm and the edge part "3" or "9" is an additional 1 mm, therefore the outer diameter would be 11 mm, Figures 1-2) for the purpose of providing a lens capable of supplying a sufficient amount of oxygen to the user and to provide a lens that is compatible with users and impermeable to bacteria (Column 3, line 62-Column 4, line 78). Therefore it would have been obvious for the lens of Domschke et al to further include the junction between the rigid and flexible portions to include an angled surface specifically a V-shaped surface, wherein the angled surfaces are angled between about 95 degrees to about 170 degrees, wherein the rigid portion has a diameter that ranges between 4.0 millimeters to about 12.0 millimeters, and wherein the substantially flexible portion has an outer diameter that ranges between about 10.0 millimeters to about 18.0 millimeters since Sohnges teaches of a hybrid contact lens comprising: a substantially

Art Unit: 2873

rigid portion; and a substantially flexible portion coupled to the substantially rigid portion at a junction; wherein the junction comprises a substantially V-shaped surface, wherein the angled surfaces are angled between about 95 degrees to about 170 degrees, wherein the rigid portion has a diameter that ranges between 4.0 millimeters to about 12.0 millimeters and wherein the substantially flexible portion has an outer diameter that ranges between about 10.0 millimeters to about 18.0 millimeters for the purpose of providing a lens capable of supplying a sufficient amount of oxygen to the user and to provide a lens that is compatible with users and impermeable to bacteria.

Regarding claims 6-8 and 47-49, Domschke et al and Sohnges disclose and teach of a contact lens as shown above and Domschke et al further discloses that the rigid portion has a gas permeability in the claimed range (Column 29, lines 23-54, wherein the rigid portion of the plasma treated lens has a gas permeability of 90), wherein the rigid portion is made of dimethylacrylamide (Column 26, lines 8-32, wherein the lens (Column 29, lines 23-54 is made according to example B1, including dimethylacrylamide), and wherein the hydrophilic portion includes poly HEMA (Column 14, line 34-Column 15, line 3).

Regarding claims 9, 50, and 70, Domschke et al and Sohnges disclose and teach of a contact lens as shown above wherein the lens can be used to correct for various vision problems (Column 1, lines 13-22, Sohnges), but do not specifically disclose that the lens is constructed to include a prescription obtained from a wavefront aberrometer. However, examiner takes judicial notice that it is well known in the art of contact lenses for the lenses to have a prescription obtained from a wavefront aberrometer, for the purpose of determining an accurate prescription for the patient. Therefore it would have been obvious to one having ordinary skill in the art at the

time the invention was made for the contact lens of lens of Domschke et al and Sohnges to further include a prescription obtained from a wavefront aberrometer since it is well known in the art of contact lenses for the lenses to have a prescription obtained from a wavefront aberrometer, for the purpose of determining an accurate prescription for the patient.

Regarding claims 10, 51, and 71, Domschke et al and Sohnges disclose and teach of a contact lens as shown above, but do not specifically disclose that the lens is constructed to include a prescription for presbyopia. However, examiner takes judicial notice that it is well known in the art of contact lenses for the lenses to include a prescription for presbyopia, for the purpose of helping the user accommodate to a change in focus of the user. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the contact lens of Domschke et al and Sohnges to further include a prescription for presbyopia since it is well known in the art of contact lenses for the lenses to include a prescription for presbyopia, for the purpose of helping the user accommodate to a change in focus of the user.

Response to Arguments

Applicant's arguments with respect to claims 1-11 and 44-61 have been considered but are moot in view of the new ground(s) of rejection in view of Domschke et al as shown above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 2873


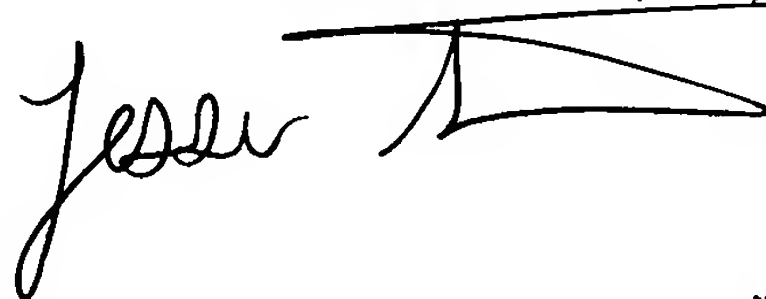
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica T. Stultz whose telephone number is (571) 272-2339. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on 571-272-2328. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica Stultz
Patent Examiner
AU 2873
August 18, 2005



JORDAN SCHWARTZ
PRIMARY EXAMINER